

Exhibit H

IN THE UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF WEST VIRGINIA
AT CHARLESTON

JO HUSKEY AND ALLAN HUSKEY,	:	
Plaintiffs,	:	CASE NUMBER
v.	:	2:12-cv-05201
ETHICON, INC., ET AL.,	:	
Defendants.	:	

TRANSCRIPT OF TRIAL - DAY EIGHT

SEPTEMBER 03, 2014

BEFORE THE HONORABLE JOSEPH R. GOODWIN,
UNITED STATES DISTRICT JUDGE

Court Reporter:	Carol Farrell, CRR, RMR, CCP, RPR (304)347-3188 carol_farrell@wvsc.uscourts.gov
	Anthony Rolland, CRR, RMR, RPR (407)760-6023 rolland.crr@gmail.com

Proceedings recorded by machine stenography; transcript
produced by computer.

<p style="text-align: right;">Page 118</p> <p>1 as a demonstrative, but I do object to it as a 1006 exhibit.</p> <p>2 THE COURT: I will admit it as an exhibit.</p> <p>3 (Defendants' Exhibit 23503 received in evidence.)</p> <p>4 BY MS. JONES:</p> <p>5 Q. Doctor, in addition to the randomized controlled studies</p> <p>6 and the long-term studies that we've just talked about, have</p> <p>7 there been other studies that have been done with respect to</p> <p>8 the TVT and the TVT-O?</p> <p>9 A. Oh, yes. There have been lots of observational studies,</p> <p>10 monitoring patients for, you know, complications, looking at</p> <p>11 the safety, that's always a big concern for physicians and</p> <p>12 surgeons.</p> <p>13 Q. And, Doctor, have there been professional organizations</p> <p>14 that have actually looked at and evaluated the studies that</p> <p>15 have been done with respect to midurethral slings?</p> <p>16 A. Yes.</p> <p>17 Q. Let me back up. Have there actually been studies that</p> <p>18 have been done to compare the Retropubic and the obturator</p> <p>19 midurethral slings?</p> <p>20 A. Yes. The TOMUS study we looked at earlier was one</p> <p>21 example.</p> <p>22 Q. And have there been studies that have specifically looked</p> <p>23 at the TVT versus the TVT-O?</p> <p>24 A. Yes.</p> <p>25 Q. And what have those studies shown about how they are</p>	<p style="text-align: right;">Page 120</p> <p>1 the studies show in the prospective comparison between the TVT</p> <p>2 and the TVT-O?</p> <p>3 A. That they're equal.</p> <p>4 Q. And, Doctor, based upon that information, do you have an</p> <p>5 opinion as to whether or not the studies evaluating the TVT</p> <p>6 are applicable or have value for the TVT-O?</p> <p>7 A. Yes. I think because it's the same material and we've</p> <p>8 shown similar efficacy that we can draw conclusions about the</p> <p>9 TVT-O by looking at the TVT studies.</p> <p>10 Q. Let me ask you one other question: We've had some</p> <p>11 discussion about laser-cut mesh. Do the studies that we've</p> <p>12 talked about with respect to the laser-cut mesh in your</p> <p>13 judgment, your opinion -- strike that. Start over.</p> <p>14 Do the studies that we've talked about with respect to</p> <p>15 the TVT-O apply equally to the TVT-O with the laser-cut mesh?</p> <p>16 A. Yes. There's really been shown no difference between the</p> <p>17 two ways that the mesh is cut, it doesn't really make a</p> <p>18 difference.</p> <p>19 Q. Do you know of any reason from a medical standpoint that</p> <p>20 the mere fact that it's laser-cut that it would pose -- that</p> <p>21 there would be any different efficacy rates?</p> <p>22 A. No.</p> <p>23 Q. Do you know of any reason from the standpoint that it's a</p> <p>24 laser-cut mesh that it would have different complication</p> <p>25 rates?</p>
<p style="text-align: right;">Page 119</p> <p>1 alike or different?</p> <p>2 A. They're very comparable. The TVT-O does have increased</p> <p>3 risk of leg pain, groin pain, but it's almost always</p> <p>4 transient, it goes away within two days to a few weeks, so</p> <p>5 that's really the only difference that we see in the TVT</p> <p>6 versus the TVT-O.</p> <p>7 Q. And, Doctor, is that complication a result of how the</p> <p>8 procedure differs in terms of the approach or implantation?</p> <p>9 MS. FITZPATRICK: Objection, Your Honor.</p> <p>10 THE COURT: Sustained. It is leading.</p> <p>11 BY MS. JONES:</p> <p>12 Q. Can you tell us, Doctor, what you attribute that</p> <p>13 difference to?</p> <p>14 A. Sure. As I talked about before, the TVT-O goes through</p> <p>15 those leg muscles, so those muscles can feel cramped, sore,</p> <p>16 inflamed right after the surgery.</p> <p>17 Q. And in contrast to that, what does the Retropubic or the</p> <p>18 TVT-O?</p> <p>19 A. And the Retropubic goes straight up and exits right</p> <p>20 behind the pubic bone.</p> <p>21 Q. And in terms of Ms. Huskey, is there any indication that</p> <p>22 Ms. Huskey suffered from leg pain or is complaining about leg</p> <p>23 pain today?</p> <p>24 A. No.</p> <p>25 Q. Now, in terms of efficacy, how well they work, what do</p>	<p style="text-align: right;">Page 121</p> <p>1 A. No.</p> <p>2 Q. All right, Doctor. I want to turn to one other area real</p> <p>3 quick with respect to the literature. As to the literature</p> <p>4 and the studies that have been done, have there been doctor</p> <p>5 organizations that have looked at the information on</p> <p>6 midurethral slings and evaluated their safety and efficacy?</p> <p>7 A. Yes.</p> <p>8 Q. And let me hand you, Doctor, what's previously been</p> <p>9 marked as defense exhibit 20218 and ask you if you're familiar</p> <p>10 with that.</p> <p>11 A. Yes, I am.</p> <p>12 Q. And tell us what that is.</p> <p>13 A. This is the position statement on mesh midurethral slings</p> <p>14 for stress incontinence put out by AUGS, the American</p> <p>15 Urogynecologic Society, and SUFU, which is the Society for</p> <p>16 Urodynamics and Female Urology. So both those organizations</p> <p>17 got together and said what's our position on this, is this</p> <p>18 procedure to be recommended or not? And the conclusion was</p> <p>19 that it is safe and effective and has improved the quality of</p> <p>20 life for millions of women.</p> <p>21 MS. JONES: Can we pull that up, please?</p> <p>22 BY MS. JONES:</p> <p>23 Q. And, Doctor, specifically what is their conclusion as</p> <p>24 stated on the first page there?</p> <p>25 A. The polypropylene mesh midurethral sling is the</p>

<p style="text-align: right;">Page 122</p> <p>1 recognized worldwide standard of care for the treatment of</p> <p>2 stress urinary incontinence. The procedure is safe,</p> <p>3 effective, and has improved the quality of life for millions</p> <p>4 of women.</p> <p>5 Q. Do you agree with that?</p> <p>6 A. Absolutely.</p> <p>7 Q. And if we turn to the -- first of all, in the</p> <p>8 introduction, what do the authors say is the purpose of this</p> <p>9 paper?</p> <p>10 A. They say that the purpose is to support the use of the</p> <p>11 midurethral sling in the surgical management of stress</p> <p>12 incontinence.</p> <p>13 Q. If we turn to the conclusion of the paper, page three,</p> <p>14 what was the conclusion of these two organizations?</p> <p>15 A. The conclusion was that it has helped millions of women</p> <p>16 with stress incontinence regain control of their lives by</p> <p>17 undergoing a simple outpatient procedure that allows them to</p> <p>18 return to daily life very quickly. With its acknowledged</p> <p>19 safety and efficacy it has created an environment for a much</p> <p>20 larger number of women to have access to treatment.</p> <p>21 Q. And, Doctor, let me just ask you, do you agree with the</p> <p>22 conclusions of the AUGS statement here?</p> <p>23 A. Yes.</p> <p>24 Q. In your judgment, based upon your training and experience</p> <p>25 and use of the TVT-O, do these conclusions apply to the TVT-O?</p>	<p style="text-align: right;">Page 124</p> <p>1 A. Yes.</p> <p>2 Q. And what is their recommendation under 1.10.3?</p> <p>3 A. The surgeon should use procedures and devices for which</p> <p>4 there is current high quality evidence of efficacy and safety.</p> <p>5 Only use a device that they have been trained to use. Use</p> <p>6 type one mesh and consider using a tape colored for high</p> <p>7 visibility.</p> <p>8 Q. Let me ask these questions. One, if you look down to</p> <p>9 footnote 11, does it identify the devices for which they</p> <p>10 determined there was current high quality evidence?</p> <p>11 A. Yes.</p> <p>12 Q. And what are those devices?</p> <p>13 A. TVT or Advantage, TVT-O, Monarch and Obtryx.</p> <p>14 Q. And then my next question is if we go up to the big part,</p> <p>15 it says use a device manufactured from type one macroporous</p> <p>16 polypropylene tape. Does the TVT-O have that type of mesh?</p> <p>17 A. Yes.</p> <p>18 Q. And where it says consider using a tape colored for high</p> <p>19 visibility, do you have any coloring on the TVT-O mesh?</p> <p>20 A. Yes. It's blue.</p> <p>21 THE COURT: Do any of the other products have a</p> <p>22 color?</p> <p>23 THE WITNESS: Yes, most of them have color now, but</p> <p>24 there are still a couple that are clear.</p> <p>25 THE COURT: All right.</p>
<p style="text-align: right;">Page 123</p> <p>1 A. Yes.</p> <p>2 Q. In your judgment, based upon your experience, do these</p> <p>3 conclusions apply to the TVT-O with the laser-cut mesh?</p> <p>4 A. Yes.</p> <p>5 Q. Now, are you also familiar, Doctor, with an organization</p> <p>6 known as NICE or NICE?</p> <p>7 A. Yes.</p> <p>8 Q. I'm handing you what's previously been received as</p> <p>9 defense exhibit 20212. And, Doctor, can you tell us what that</p> <p>10 document is?</p> <p>11 A. Yes. This is put out by the National Institute for</p> <p>12 Health and Care Excellence, and it's a guideline, a clinical</p> <p>13 guideline for the management of urinary incontinence in women.</p> <p>14 THE COURT: Ms. Jones.</p> <p>15 MS. FITZPATRICK: I need a copy.</p> <p>16 MS. JONES: I'm sorry. I thought I had handed it.</p> <p>17 BY MS. JONES:</p> <p>18 Q. If you look at page 24 of that document, Doctor, was the</p> <p>19 group looking at and examining synthetic tapes?</p> <p>20 A. Yes.</p> <p>21 Q. And in terms of the synthetic tapes, what type of tapes</p> <p>22 was it referring to here?</p> <p>23 A. They specifically refer to the type one macroporous</p> <p>24 polypropylene tape of which TVT and TVT-O are types of that.</p> <p>25 Q. And specifically were they looking at midurethral slings?</p>	<p style="text-align: right;">Page 125</p> <p>1 BY MS. JONES:</p> <p>2 Q. Doctor, I want to turn to a little bit of a different</p> <p>3 subject matter. I want to talk with you about Ms. Huskey. I</p> <p>4 think you told us you had an opportunity to examine her?</p> <p>5 A. Yes, I did.</p> <p>6 THE COURT: Why don't we break here? It seems we</p> <p>7 just switched topics and it's two minutes till.</p> <p>8 Ladies and gentlemen, we'll take our lunch break.</p> <p>9 I'll ask you to be back at ten minutes after 1:00. Have a</p> <p>10 nice lunch.</p> <p>11 Don't talk about the case among yourselves or permit</p> <p>12 anyone to discuss it with you or in your presence. Don't read</p> <p>13 anything, watch anything, listen to anything, use any social</p> <p>14 media or do any research. Have a nice lunch.</p> <p>15 Counsel, do you have anything for me?</p> <p>16 MR. THOMAS: Yes, Your Honor. Just briefly.</p> <p>17 THE COURT: All right. You're excused, ladies and</p> <p>18 gentlemen.</p> <p>19 (The Jury left the courtroom at 11:58 a.m.)</p> <p>20 THE COURT: Could I have a representative of the</p> <p>21 plaintiffs' team?</p> <p>22 MR. WALLACE: Sorry, Judge.</p> <p>23 MR. THOMAS: Your Honor, I'd like to offer the</p> <p>24 as-read deposition transcript of Dr. Elizabeth Mueller and the</p> <p>25 as-played transcript of Dr. Aaron Kirkemo.</p>

REPORTERS' CERTIFICATE

Carol Farrell, CRR, RMR, CCP, RPR, Official Court
Reporter of the United States District Court for the Southern
District of West Virginia, and Anthony Rolland, CRR, RMR, RPR,
do hereby certify that the foregoing is a true and accurate
transcript, to the best of our ability, of the proceedings as
taken stenographically by and before us at the time, place,
and on the date hereinbefore set forth.

/S/ Carol Farrell, CRR, RMR, CCP, RPR 09/03/14

Court Reporter Date

/S/ Anthony Rolland, CRR, RMR, RPR 09/03/14

Court Reporter Date